

K071105



JUL 30 2007

510(k) Summary

Device Proprietary Name:	OsteoMed Calcaneal Plate and Screw Fixation System
Device Common Name:	Bone Plate
Classification Name:	HRS, Plate, Fixation, Bone
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Piedad Peña
Date Prepared:	July 27, 2007

Summary:

This submission describes the OsteoMed Calcaneal Plate and Screw Fixation System indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures.

The OsteoMed Calcaneal Plate and Screw Fixation System is comprised of various plates and screws. Plates are provided in a variety of arm configurations, in a variety of sizes in lengths of 45mm through 76mm and thickness of 1.0mm through 2.0mm. Screws to be provided in this system are 3.0mm and 3.5mm diameter in lengths of 18mm through 55mm with either standard or locking features. Plates are made of Titanium (ASTM F-67) or Titanium Alloy (ASTM F-136). The Screws are made of Titanium Alloy (ASTM F-136). Drill guides, pilot drills, depth gauge, drivers, bending pliers, plate cutters, guide wires and preparation instruments will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to: Synthes K991407, New Deal K041786 and Darco K061808.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Calcaneal Plate and Screw Fixation System does not raise any new safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OsteoMed L.P.
% Ms. Piedad Peña
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

JUL 30 2007

Re: K071105
Trade/Device Name: OsteoMed Calcaneal Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 2, 2007
Received: July 3, 2007

Dear Ms. Pena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Ms. Piedad Peña

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a small "to" written below the signature.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071105

Device Name: OsteoMed Calcaneal Plate and Screw Fixation System

Indications for Use:

The OsteoMed Calcaneal Plate and Screw Fixation System is intended for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures. Plates and screws are intended for single use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Page ___ of ___

(Posted November 13, 2003)

510(k) Number K071105